

Doc Code: AP PRE REQ

PTO/SB/33 (07-05)

Approved for use through 05/31/2008. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional)

S63.2B-9720-US01

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)]

on 6-12-2008

Signature

Wendy Steinborn

Typed or printed name Wendy Steinborn

Application Number

09/682865

Filed

10/25/2001

First Named Inventor

Stefan Pallazza

Art Unit

3734

Examiner

Vi X. Nguyen

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s)

Note: No more than five (5) pages may be provided.

I am the

☐

applicant/inventor

☐

assignee of record of the entire interest.

See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.
(Form PTO/SB/96)

☒

attorney or agent of record

Registration number 54,439

☐

attorney or agent acting under 37 CFR 1.34

Registration number if acting under 37 CFR 1.34 _____

James L. Shands
Signature

James L. Shands

Typed or printed name

952-563-3000

Telephone number

6-12-2008

Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☐

*Total of _____ forms are submitted.

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2

REASONS FOR PRE-APPEAL REQUEST FOR REVIEW

Claims 1 – 9, 11, 12, 14, 22, 28, 29, and 64 – 67 are pending in this application. Claims 10, 13, 15, 20, 21, 24 – 27, and 30 – 63 were withdrawn from consideration. Claims 7 – 9, 28, and 29 were objected to as being dependent upon a rejected base claim, but were said to contain allowable subject matter. Claims 1 – 6, 11, 12, 14, 22, and 64 – 67 were rejected in the Office Action mailed 3/17/08.

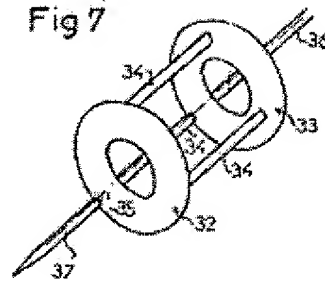
Claim Rejections—35 U.S.C. §102(b)**Guiset, U.S. Patent No. 4,183,102**

In the Office Action mailed 3/17/08, the Office rejected claims 1, 5, 14, and 64 under 35 U.S.C. § 102(b), alleging the same to be anticipated by U.S. Patent No. 4,183,102 to Guiset (hereafter “Guiset”).

Claim 1

Claim 1 of the present application is directed toward a device for configuring an inflatable balloon of a balloon catheter assembly. The device comprises a body comprising a **plurality of inflatable members** defining a channel therebetween, the plurality of inflatable members disposed about the channel and configured to contain at least a portion of an inflatable balloon of a balloon catheter within the channel, each inflatable member having a balloon contacting portion, **wherein each inflatable member extends part of the way about the channel but does not encircle the channel**; and a housing configured to constrain the plurality of inflatable members as the plurality of inflatable members inflate inwardly into the channel.

The Examiner, in making the § 102(b) rejection over Guiset, stated that FIG. 7 of Guiset discloses “quite clearly, the inflatable members **extend part of the way** about the channel **but does not encircle the channel**, and where a housing 26 is able to constrain the plurality of inflatable members.” (Emphasis added). FIG. 7 is presented immediately below:



Contrary to the Examiner's assertion, it appears to Applicant that the sleeves 32 and 33 of FIG. 7, which presumably the Examiner is asserting to be the inflatable members of instant claim 1, do indeed entirely encircle a "channel." As such, FIG. 7 of Guiset fails to teach or suggest all the limitations of instant claim 1.

Second, assuming for the sake of argument that the Office mistakenly referred to FIG. 7 instead of FIG. 8, FIG. 8 also does not teach or suggest all the limitations of instant claim 1. Claim 1, as amended above, states that the "housing [is] configured to constrain the plurality of inflatable members as the plurality of inflatable members inflate inwardly into the channel." However, Guiset states at col. 6, line 66 – col. 7, line 6,

Means are also provided for introducing a gas, when desired, into the different chambers 50, either simultaneously or successively, in order to cause the chambers to inflate. As a result of the inflation and the consequent increase in the circumferential dimensions of the membranes 45 to 47, a simultaneous increase in the external diameter of the external face 39 and in the internal diameter of the internal face 38, which defines the channel 51, results.

(Emphasis added).

That is, the internal face 38 of Guiset expands radially outward as the chambers are inflated. This is in accordance with the purpose of the device in Guiset: "the invention finds use wherever it is essential to alleviate, either temporarily or permanently, an injury or defect to the wall of a passage while still permitting the circulation through the passage of the substances which should flow through it." (Guiset, col. 1, line 14 – 19)(Emphasis added). It would be in direct contravention of the purpose of the Guiset device if the internal face 38 expanded inwardly upon inflation; this would constrict the passageway, thereby inhibiting the flow of material therethrough. As such, Guiset does

not teach or suggest all the elements of instant claim 1. Accordingly, Applicant respectfully requests withdrawal of the rejection.

Claim 5

For at least the reasons presented above with respect to independent claim 1, independent claim 5 is also not anticipated by Guiset. Accordingly, Applicant requests the removal of the rejection.

Claim 14

Claim 14 includes the limitation, “the inflatable members inflatable from a first size to a second size in which the inflatable members apply an inward force to a balloon of a balloon catheter assembly disposed in the channel.” As argued above with respect to claim 1, Guiset does not teach or suggest inflatable members that can apply an inward force to a balloon within the channel. Rather, Guiset expands radially outward so that the channel is not constricted. Thus, Guiset does not anticipate claim 14. Accordingly, Applicant requests the removal of the rejection.

Claim 64

Claim 64 includes the limitation, “the inflatable members inflatable inward so as to reduce in area a cross-section of the channel.” As argued above with respect to claim 1, Guiset does not teach or suggest inflatable members that inflate inward. Rather, Guiset expands radially outward so that the channel is not constricted and therefore not “reduce[d] in area a cross-section of the channel,” as recited in claim 64. Thus, Guiset does not anticipate claim 64. Accordingly, Applicant requests the removal of the rejection.

Tsukashima et al. (hereafter “Tsukashima”), U.S. Patent No. 5,350,361

The Office rejected claims 1 – 6, 11, 12, 14, 22, and 64 – 67, alleging the same to be anticipated by Tsukashima.

Claims 1 – 4, 6, 11, 12, and 22

The rejection of claims 1 – 6, 11, 12, 14, 22, and 64 – 67 by the Office is notably similar to the Examiner’s rejections in the Office Actions mailed September 19,

2006 and August 9, 2007. The Examiner has confused the **configured balloon** with the **device for configuring an inflatable balloon**.

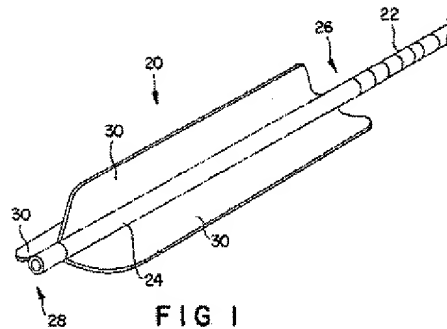
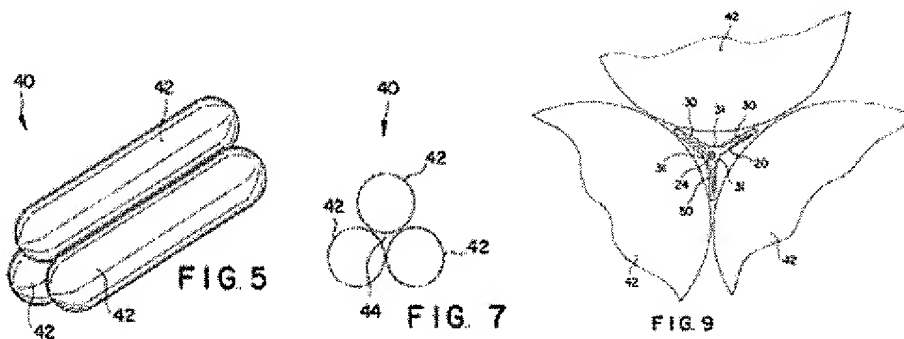


FIG. 1 of Tsukashima, presented immediately above, shows the **configured inflatable balloon** 20 with “flaps or wings 30” (Tsukashima, col. 4, lines 44 – 45).

FIGs 5, 7, and 9 of Tsukashima are shown immediately below:



FIGs. 5 and 7 of Tsukashima show the **device for configuring inflatable balloon** 20. The three cylindrical pins 42 “are made of stainless steel or another suitably rigid material,” rather than being inflatable as in claim 1. (Tsukashima, col. 4, lines 64 – 65). FIG. 9 shows the **inflatable balloon 20 being configured by the device for configuring** the inflatable balloon. Thus, Tsukashima plainly does not teach or suggest a device for configuring an inflatable balloon of a balloon catheter assembly **in which the device for configuring** comprises a body comprising a plurality of inflatable members defining a channel therebetween, as in claim 1. As such, claims 1 – 4, 6, 11, 12, and 22 are not anticipated by Tsukashima.

Claim 5

For at least the reasons presented above with respect to independent claim 1, independent claim 5 is also not anticipated by Tsukashima. Accordingly, Applicant requests the removal of the rejection.

Claim 14

For at least the reasons presented above with respect to independent claim 1, independent claim 14 is also not anticipated by Tsukashima. Accordingly, Applicant requests the removal of the rejection.

Claims 64 – 67

For at least the reasons presented above with respect to independent claim 1, independent claim 64 and those claims dependent therefrom are also not anticipated by Tsukashima. Accordingly, Applicant requests the removal of the rejection.

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

Date: June 12, 2008

By: 

James L. Shands
Reg. No.: 54,439

6640 Shady Oak Dr., Suite 400
Eden Prairie, MN 55344-7834
Telephone: (952) 563-3000
Facsimile: (952) 563-3001

f:\wpwork\jls\9720us01_preappeal_brief_20080428.doc